PTO/SB/21 (02-04)

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Approved for use through 07/31/2006. OMB 0651-0031
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70

Attorney Docket Number

# **TRANSMITTAL FORM**

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Total Number of Pages in This Submission

Filing Date July 9, 2001 First Named Inventor J. J. SEILHAMER Art Unit 1635 Examiner Name J. Epps Ford

ENCLOSURES (Check all that apply)				
X Fee Transi	mittal Form (1 page +	Drawing(s)	After Allowance communication to Technology Center (TC)	
Fee	Attached	Licensing-related Papers	Appeal Communication to Board of Appeals and Interferences	
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Express Abandonment Request  Information Disclosure Statement  Certified Copy of Priority Document(s)  Response to Missing Parts/ Incomplete Application		Request for Refund  CD, Number of CD(s)  Remarks  CUSTOMER NO. 25225	Copy of U.S. Patent 6,613,886 (53 pages) Copy of Discussion on Antibodies (6 pages) Return Receipt Postcard	
Response to Missing Parts under 37 CFR 1.52 or 1.53		COSTOMER NO. 25225		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT				
Firm or Individual name	MORRISON & FOERSTER LLP Kate H. Murashige - 29,959			
Signature	Gott W. Mussly			
Date	July 28, 2004	U		

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#### **Example 16: Antibodies**

Specification: The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

Claim: An isolated antibody capable of binding to antigen X.

## Analysis:

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

A search of the prior art indicates that antigen X is novel and unobvious.

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.

**Conclusion:** The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.

#### **Example 16: Antibodies**

**Specification:** The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

Claim: An isolated antibody capable of binding to antigen X.

## **Analysis:**

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

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A search of the prior art indicates that antigen X is novel and unobvious.

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Conclusion: The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.

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Claim: An isolated antibody capable of binding to antigen X.

## Analysis:

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

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**Conclusion:** The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.